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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,803	04/21/2006	Mary J. Champion	D-3150	5915

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12/03/2007

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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12/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,803	Applicant(s) CHAMPION, MARY J.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,35,36,38,41,44,45,55,57-59,61-65 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,38,41,44,45,55,57-59,61-65 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE and amendment, both filed 10/29/2007.

Claims 1-32, 34, 37, 39, 40, 42, 43, 46-54, 56, 60, and 66 have been canceled.

Claims 67-70 have been added.

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 67-70 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered.

Specification

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 67-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hot flashes, does not reasonably provide enablement for preventing hot flashes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is method for preventing hot flashes in women prone to hot flashes. The entire specification disclosed treatment of hot flashes. Nowhere in the specification applicant disclosed prevention of

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hot flashes. Further, the specification does not enable the prevention of the hot flashes in women prone or susceptible to hot flashes.

The breadth of the claims: The claims are very broad. The claim encompasses prevention of hot flashes in susceptible patients, and the burden of enabling prevention of hot flashes would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to hot flashes. The prevention of hot flashes may or may not be addressed by the administration of the instant patch because not all menopausal women experience hot flashes, which are one of various symptoms of menopausal syndrome.

The state of the prior art: The state of the art recognized treatment of hot flashes using the gel patches BeKool, and does not recognize the administration of BeKool patches to prevent hot flashes as required in the instant claims. The state of the art recognizes the treatment of hot flashes as a symptom of menopausal syndrome, but not its cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent hot flashes is absent. Guidance for treatment of hot flashes as a symptom of menopausal syndrome is provided, however, no evidence is provided that hot flashes actually have been prevented. Furthermore, the specification provides no guidance, in the way written description, on prevention of hot flashes, only treatment of hot flashes as a symptom, and it is not obvious from the disclosure of treatment of a symptom if their prevention by applying the same patch even before their

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occurrence will work. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the methods of using fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing hot flashes using the instant patches makes practicing the claimed invention unpredictable in terms of the prevention of the occurrence of the hot flashes even before been experienced by women.

The presence or absence of working examples: The specification discloses treatment of hot flashes. No working examples to show preventing hot flashes. Therefore, the specification has enabled only treating hot flashes as a symptom of menopausal syndrome when they are present, and not their prevention before their occurrence, because they may not occur in all menopausal women.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for preventing hot flashes without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 33, 35, 41, 44, 45, 61, 63, 69 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by the product "BeKool" by Kobayashi Healthcare, INC., and was presented as: "Product Concept Test".

BeKool is cooling gel sheet used for treating hot flashes. The presentation implies that the gel sheets been in use before the article date August 14, 2003. BeKool picture shows the product is packaged, and instruction is provided. The pamphlet of the product, "Immediate, convenient and discrete relief from hot flashes ... anywhere anytime", stated that "If and when a hot flash occurs, simply peel off the strip covering the adhesive backing, apply the cooling soft gel sheet to the rear of the neck under your clothing". Therefore, instruction is provided. The present method of treating requires only the step of applying the patch. The site of application of the patch in the upper back or between the clavicles does not impart patentability to the claimed method because the patch will work the same way effectively and equally regardless of the site of its application. Additionally, applicant disclosed in page 4, lines 15-20 that: "Although the exemplary embodiment of the invention is directed to placing the cooling device on the back of a woman, the cooling device may be placed on any site of a woman's body,

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preferably on or at any hot flash origin site, or a site where the hot flash, for example, the first symptom of the hot flash, is felt first". Applicants further disclosed and claimed applying the patch between C3 vertebrae and T6 vertebrae, therefore, application on the back of the neck (C vertebrae) is within the scope of the present invention. BeKool does not contain any active agent in the gel sheet. BeKool is an adhesive sheet as implied by the instruction pamphlet.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 36, 38, 55, 57-59, 62, 64, 65, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over "BeKool" product in view of any of JP 2002119529 ('529) or US 6,224,899 ('899).

The BeKool product is described under 35 U.S.C. 102 rejection as set forth in this office action.

However, BeKool does not describe the gel as water containing gel comprising polyacrylic component and gas permeable substrate as claimed by claims 36, 38, 55, 57-59, 62, 64, 65, 67 and 68.

JP '529 teaches cooling patch which can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, said patch comprises water permeable film covered with hydrous paste of polyacrylic acid (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-61). The cooling patch can be applied locally to the area of discomfort without limitation to the body part such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel adhesive sheet to treat hot flashes as disclosed BeKool, and made the sheet of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by JP '529 or US '899, motivated by the teaching of JP '529 that such a cooling patch structure and materials can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, or motivated by the teaching of US '899 that such an adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue, with reasonable expectation of having cooling patch or sheet comprising water permeable backing and polyacrylic acid paste or gel that is able to maintain the cooling

effect and preserve the coolness of the site of its application to treat hot flashes successfully and effectively.

Response to Arguments

9. Applicant's arguments with respect to claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 have been considered but are moot in view of the new ground(s) of rejection.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,956,963 disclosed treatment of hot flashes using wrist cooler. The article by "Pharmacy Key", September 2003 disclosed under "Lidocaine" that the patch containing lidocaine can be applied on intact skin on the back.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

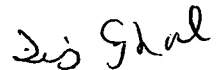
you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615



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ISIS GHALI
PRIMARY EXAMINER